REMARKS

Claim Status

Claims 1-36 and 71 are pending in the present application. The remaining claims, including the Examiner-renumbered Claims 72-78, have been withdrawn from consideration in response to a previous Restriction/Election requirement. No additional claims fee is believed to be due.

The Abstract

The Abstract is objected to because it contains two paragraphs, and more than 150 words. A NEW Abstract is attached hereto as a separate paper. The new abstract is one (1) paragraph and approximately 150 words. Thus, the objection has been overcome and the Applicants respectfully request that the objection be withdrawn.

Rejection Under 35 USC §112, Second Paragraph

Claims 1-10, 13-14, 16, 19-20, 22 and 25 are rejected under 35 USC §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention.

The Examiner asserts that the phrase "at least about" is relative and therefore indefinite. The Examiner interprets the phrase "at least" to require a definite minimum amount. The Examiner also confusingly states that "about" is interpreted to be anywhere from 0.1 – 2%.

The Applicants respectfully traverse the rejections.

Initially, it appears that the grouping of claims rejected is incorrect.

Claims 3, 4, 5, and 6 do not contain either the term "about" or the phrase "at least about". Therefore the rejections are inappropriate with respect to these Claims, and the Applicants respectfully request withdrawal of the rejections.

With respect to Claims 1, 2, 7-10, 13, 14, 16, 19, 20, 22 and 25, it appears that Claim 21 should also be included in this grouping, as Claim 21 contains the phrase "at least about".

Therefore, the Applicants will address the rejections as they apply to Claims 1, 2, 7-10, 13, 14, 16, 19-22, and 25, and respectfully traverse the rejections. The Examiner cites no authority whatsoever, neither MPEP nor case law, for the confusing interpretations and limitations asserted in the rejections.

In MPEP § 2173.05(b), relative terminology is discussed. The fact that claim language, including terms of degree, may not be precise, does not automatically render the claim indefinite under 35 USC § 112, 2nd paragraph. MPEP citing *Seattle Box Co., v. Industrial Crating & Packing, Inc.* 731 F.2d 818, 221 USPQ 568 (Fed. Cir. 1984). Furthermore, as a general proposition, broadening modifiers are standard tools in claim drafting. MPEP § 2173.05(b).

Particularly also, the term "about" and the phrase "at least about" are discussed in MPEP § 2173.05(b). "At least about" was only held indefinite when there was close prior art and nothing in the specification, prosecution history, or prior art to provide any indication as to what range of specific activity was covered by the therm "about". MPEP § 2173.05(b) citing *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991).

In looking for a definition for the term "about" the *Amgen* court looked to the specification of the patent at issue and the prior art in the relevant field to attempt to determine what one of ordinary skill in the art would understand regarding the technology and results at issue.

In *Amgen*, no tolerance or limitation for the term "about" could be found at all in the specification, prosecution history *or prior art. No preferred ranges were initially given for the limitation at issue in Amgen.*

That is not the case with the present invention. The present specification provides context and definition of the term "about" and the phrase "at least about". Various example ranges for ratio of stiffening agent to lipase inhibitor, and ranges for the amounts

of stiffening agent and lipase inhibitor are provided in the specification. Therefore, one of skill in the art would understand the scope of the invention.

Furthermore, the Examiner confusingly cites that "about" is interpreted in the Claims "to be anywhere within for example about 2% means from anywhere from 0.1% to 2%". The rejection itself is confusing and unclear, and the Examiner provides no context for how such an interpretation was determined or what the given range relates to – ratio of stiffening agent to lipase inhibitor, or amounts of each. In *Amgen* the court specifically did not enumerate any standard or particular reach or percentage of tolerance of the term "about". In the present invention, none of the rejected Claims recites "about" or "at least about" 2% of anything.

Therefore, in the context of the present Claims, there are various example ranges for ratio of stiffener to lipase inhibitor provided in the specification, as well as various example ranges for the amounts of stiffening agent and lipase inhibitor provided in the specification. Thus, there is context and definition for the term "about" and the phrase "at least about" in the present specification. Therefore, the rejections are overcome and the Applicants respectfully request withdrawal of the rejections.

Rejection Under 35 USC §102(e) Over de Smidt et al.

1. Claims 1-6, 8, 10, 11, and 21 are rejected under 35 USC §102(e) as being anticipated by US Patent 6,703,369 to de Smidt et al. ("de Smidt").

The Applicants respectfully traverse the rejection. In order for an anticipation rejection to stand, the cited reference must disclose and teach each an every element of the claim. See MPEP § 2131. A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. MPEP § 2131 citing *Verdegall Bros. v. Union Oil Co. of California* 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

De Smidt teaches only compositions having a lipase inhibitor and a fatty acid ester of a polyol. However, de Smidt does not teach any particular relationship or ratio between the two. De Smidt only teaches that the lipase inhibitor is present at amounts between 1% and 50%, and that the fatty acid ester is present in an amount between 0.5% and 90%. Though broad ranges of amounts of lipase inhibitors and broad ranges of

amounts of fatty acid esters are given, no particular or optimum ratios of the two are provided.

In contrast, the present invention, as in Claim 1, recites a specific ratio of stiffening agent to lipase inhibitor of at least about 4.5:1. This ratio is not disclosed by de Smidt. Therefore, de Smidt does not disclose each and every element of the claimed invention, and thus, de Smidt can not anticipate the present invention. The Applicants therefore request that the rejection be withdrawn.

2. Claims 13-19 and 23 are rejected under 35 USC §102(e) as being anticipated by de Smidt.

De Smidt teaches only compositions having a lipase inhibitor and a fatty acid ester of a polyol. However, de Smidt does not teach any particular relationship or ratio between the two. De Smidt only teaches that the lipase inhibitor is present at amounts between 1% and 50%, and that the fatty acid ester is present in an amount between 0.5% and 90%. Though broad ranges of amounts of lipase inhibitors and broad ranges of amounts of fatty acid esters are given, no particular or optimum ratios of the two are provided.

In contrast, the present invention, as claimed in Claim 13, recites a specific ratio of stiffening agent to lipase inhibitor of at least about 1:1. This ratio is not disclosed by de Smidt. Therefore, de Smidt does not disclose each and every element of the claimed invention, and thus, de Smidt can not anticipate the present invention. The Applicants therefore request that the rejection be withdrawn.

3. Claims 25-27, 29, and 30 are rejected under 35 USC §102(e) as being anticipated by de Smidt.

The Applicants respectfully traverse the rejection. De Smidt does not disclose a composition for stiffening lipophilic substances. De Smidt only discloses a lipase inhibitor in combination with a fatty acid ester of a polyol. Therefore, because de Smidt does not disclose a stiffening agent for stiffening lipophilic substances in the gastrointestinal tract of an animal, de Smidt does not disclose the composition as claimed

and thus does not anticipate the Claims. Therefore, the Applicants respectfully request that the rejection be withdrawn.

4. Claims 31-33, 35, and 36 are rejected under 35 USC §102(e) as being anticipated by de Smidt.

The Applicants respectfully traverse the rejection. De Smidt does not disclose a composition for stiffening lipophilic substances. De Smidt only discloses a lipase inhibitor in combination with a fatty acid ester of a polyol. Therefore, because de Smidt does not disclose a stiffening agent for stiffening lipophilic substances in the gastrointestinal tract of an animal comprising the recited compounds, de Smidt does not disclose the composition as claimed and thus does not anticipate the Claims. Therefore, theApplicants respectfully request that the rejection be withdrawn.

Rejection Under 35 USC §103(a) Over de Smidt in view of Maeder

Claims 1-12, Claims 13 -24, and Claims 25-30 are rejected under 35 USC §103(a) as being unpatentable over US Patent 6,703,369 to de Smidt et al. ("de Smidt") in view of US Patent No. 6,730,319 to Maeder et al. ("Maeder").

The Applicants respectfully traverse the rejections. The Examiner has not met the burden of establishing a *prima facie* case of obviousness. See MPEP § 2143.01. In order for a *prima facie* case of obviousness to be established, three criteria must be met. First, there must be some suggestion or motivation, i.e. desirability, either in the references themselves, or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references must teach or suggest all of the claim limitations.

1. Claims 1-12

Initially, the Examiner states that "the instant method differs from the de Smidt teaching...". None of Claims 1-12 is a method claim. Thus, the Applicant will address the compositions. Furthermore, the Examiner, at page 8, discusses a "lipase to stiffening ratio as in claim 7", when there is no such ratio recited in Claim 7.

Neither de Smidt nor Maeder teaches or suggests the stiffening agents as rectied in Claim 1. De Smidt teaches only compositions including lipase inhibitors in combination with fatty acid esters of polyols as a second component. See Column 2, lines 43-50. Maeder teaches only fatty acids and fatty acid salts, particularly sodium and potassium salts thereof, as a second component in addition to a lipase inhibitor. See Column 3, starting at line 12.

Neither cited document teaches or suggests the particular ratio of stiffening agents to lipase in as recited in Claim 1. Both cited documents only disclose broad ranges of amounts of a broad group of lipase inhibitors and a broad group of secondary components. Thus, neither document provides any reasonable expectation of success for using any particular stiffening agent of Claim 1 in any particular ratio with a lipase inhibitor.

Furthermore, the Examiner asserts that a skilled artisan would be motivated to determine "the optimum amounts to get the maximum effect" but does not refer to amounts of what, what effect, or what "maximum" would be. The effect desired by de Smidt is to enhance the effectiveness of the lipase inhibitor. The effect desired by Maeder is to allow the lipase inhibitor to melt at a lower temperature and be distributed as a liquid in the body. Thus, there would potentially be different optimization criteria for the different desired effects, and therefore, one would not arrive at the present invention by mere optimization of the teachings and disclosure of either de Smidt or Maeder, taken either alone or in combination.

Finally, the cited documents do not disclose every element of the claimed invention. Namely, neither de Smidt nor Maeder discloses or suggests all of the stiffening agents of the present invention, nor the particular claimed ratio.

Even assuming *arguendo* that one were to combine de Smidt and Maeder one would still fall short of the Applicants' claimed invention. Therefore, the rejection has been overcome and the Applicants respectfully request withdrawal of the rejection.

2. Claims 13-24

Initially, the Examiner states that "the instant method differs from the de Smidt teaching...". None of Claims 13-24 is a method claim. Thus, the Applicant will address the compositions. Furthermore, the Examiner, at page 9, discusses range of the "lipase to stiffening ratio as in claim 20-21", when there is no such ratio recited in either Claim 20 or Claim 21.

Neither de Smidt nor Maeder teaches or suggests the stiffening agents as rectied in Claim 1. De Smidt teaches only compositions including lipase inhibitors in combination with fatty acid esters of polyols as a second component. See Column 2, lines 43-50. Maeder teaches only fatty acids and fatty acid salts, particularly sodium and potassium salts thereof, as a second component in addition to a lipase inhibitor. See Column 3, starting at line 12.

Neither cited document teaches or suggests the particular ratio of stiffening agents to lipase in as recited in Claim 13. Both cited documents only disclose broad ranges of amounts of a broad group of lipase inhibitors and a broad group of secondary components. Thus, neither document provides any reasonable expectation of success for using any particular stiffening agent of Claim 13 in any particular ratio with a lipase inhibitor.

Furthermore, the Examiner asserts that a skilled artisan would be motivated to determine "the optimum amounts to get the maximum effect" but does not refer to amounts of what, what effect, or what "maximum" would be. The effect desired by de Smidt is to enhance the effectiveness of the lipase inhibitor. The effect desired by Maeder is to allow the lipase inhibitor to melt and be distributed as a liquid in the body. Thus, there would potentially be different optimization criteria for the different desired effects, and therefore, one would not arrive at the present invention by mere optimization of the teachings and disclosure of either de Smidt or Maeder, taken either alone or in combination.

Finally, the cited documents do not disclose every element of the claimed invention. Namely, neither de Smidt nor Maeder discloses or suggests all of the stiffening agents of the present invention, nor the particular claimed ratio.

Even assuming, *arguendo*, that one were to combine de Smidt and Maeder one would still fall short of the Applicants' claimed invention. Therefore, the rejection has been overcome and the Applicants respectfully request withdrawal of the rejection.

3. Claims 25-30

Again, the Examiner states that "the instant method differs from the de Smidt teaching...". None of Claims 25-30 is a method claim. Thus, the Applicant will address the compositions.

There is no teaching or suggestion in either de Smidt or Maeder to use any sort of stiffening agent alone to stiffen lipophilic substances in the gastrointestinal tract. Both de Smidt and Maeder require a combination of lipase inhibitor and additional components that enhance the function of the lipase inhibitor or depress the melting point of the lipase inhibitor. Therefore, because there is no teaching or suggestion in either document to use a stiffening agent such as the stiffening agents of the present invention, alone, for stiffening lipophilic substances present in the gastrointestinal tract, there can be no expectation of success for compositions comprising such a stiffening agent. Thus, the cited documents do not disclose all of the claim limitations.

Assuming, *arguendo*, that one could combine de Smidt and Maeder, one would not arrive at the present invention. Thus, the rejection has been overcome and the Applicants respectfully request that the rejection be withdrawn.

4. Claims 31-36 and 71

Claims 31-36 and 71 are stated as rejected under 35 USC §102(e) as being unpatentable over de Smidt in view of Maeder and US Patent 6,358,522 to Hug et al. ("Hug"). The Applicants will assume, for purposes of expediting prosecution, that based on the language of the rejection, the rejection should read that Claims 31-36 and 71 are rejected under 35 USC §103(a).

With respect to Claims 31-36, there is no teaching or suggestion in de Smidt, Maeder, or Hug to use any sort of stiffening agent, alone, to stiffen lipophilic substances in the gastrointestinal tract. De Smidt, Maeder, and Hug all require a combination of lipase inhibitor and additional components to enhance the function of the lipase inhibitor or to lower the melting point of the lipase inhibitor. Therefore, because there is no teaching or suggestion in any of the cited documents to use a stiffening agent alone, for stiffening lipophilic substances in the gastrointestinal tract, there can be no expectation of success for using such a stiffening agent alone in such a composition. Thus, the cited documents do not disclose all of the claim limitations.

Particularly with respect to Hug and Claim 71, the Examiner states that Hug teaches one (or more) additive(s) of the group consisting of substantially non-digestable food grade thickeners and emulsifiers, and excipients. Hug teaches only the combination of a lipase inhibitor and one or more substantially non-digestable, substantially non-fermentable hydrophilic and/or hydrocolloidal food grade additives such as conventional thickeners and emulsifiers. Nowhere does Hug teach, suggest or define any type of foam compound as considered to be a conventional food grade thickener or emulsifier. See Hug, for example at column 2, line 25 through column 3, line 43.

Therefore, there is no teaching or suggestion in de Smidt, Maeder, or Hug to use any sort of stiffening agent in combination with a lipase inhibitor and an open-celled polymeric foam. Because there is no teaching or suggestion at all, in any of the cited documents, to use a polymeric foam, there can be no expectation of success for using such a foam.

Finally, the cited documents do not disclose all of the claim limitations. For example, none of de Smidt, Maeder, or Hug teaches or suggests anything with respect to an open-celled polymeric foam.

Even assuming *arguendo* that one could combine the teachings of the cited documents, at best, one might arrive at a composition having a lipase inhibitor, a fatty acid/fatty acid salt, and a non-digestable food grade thickener, but one would not arrive at

the presently claimed invention. Therefore, the rejection has been overcome and the Applicants respectfully request withdrawal of the rejection.

Conclusion

In light of the above remarks and new Abstract, it is requested that the Examiner reconsider and withdraw the objections and rejections. Early and favorable action in the case is respectfully requested.

This response represents an earnest effort to place the application in proper form and to distinguish the invention as now claimed from the applied documents. In view of the foregoing, reconsideration of this application, entry of the amendments presented herein, and allowance of all pending Claims is respectfully requested.

Respectfully submitted,

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NEW ABSTRACT

Disclosed are compositions, methods, and kits for treating conditions including; ameliorating side effects associated with compounds such as lipase inhibitors; gastrointestinal distress; fecal urgency; obesity; hyperlipidemia; diarrhea; reducing levels of toxic substances; reducing blood cholesterol levels; inducing satiety; effecting weight loss; effecting weight control; and treating, delaying onset and/or preventing Type II diabetes. One embodiment includes compositions for administration to an animal for stiffening lipophilic substances in the gastrointestinal tract. Such stiffening agents have a complete melting point of about 33°C or greater. Kits comprising the composition are also included. Methods of stiffening lipophilic substances present in the gastrointestinal tract of an animal are also provided. The methods comprise administering a composition comprising a safe and effective amount of a stiffening agent to an animal. The methods also comprise administering a composition comprising a safe and effective amount of a stiffening agent and a safe and effective amount of a lipase inhibitor to an animal.